**Application No.: 10/661,641** 

Response to Office Action dated June 7, 2006

#### **REMARKS**

#### **Status of Claims**

Claims 1-22 and 26 are canceled.

Claims 23, 25, 27, 28, 30, 32, 34 and 36 are currently amended.

Claims 23–25 and 27–37 are pending.

### Double Patenting Over U.S. Patent No. 6,622,047

Claims 23–37 are rejected in the Office Action for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,622,047. Applicants will submit an appropriate Terminal Disclaimer to obviate this nonstatutory obviousness-type double patenting rejection. It is respectfully requested that the requirement for this Terminal Disclaimer be held in abeyance until the claims are considered to be allowable but for this ground of rejection.

## Provisional Double Patenting Over U.S. Patent Application No. 10/661,640

Claims 23–37 are provisionally rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 22–37 of copending Application No. 10/661,640. Since the allegedly conflicting claims of 10/661,640 have not yet been allowed, if this rejection is maintained in view of the current amendments, it is respectfully requested that this rejection be held in abeyance until the claims of this application, or those of 10/661,640, are deemed allowable but for this ground of rejection. Applicants respectfully submit that this rejection is obviated by the present claim amendments.

### Claim Rejections Under 35 U.S.C. § 102(b)

Claims 23–37 stand rejected as being unpatentable over U.S. Patent No. 5,299,569 (Wernicke et al.). The Office Action maintains that the Wernicke device is considered to encompass all of the structure of Applicants' claims. In reply, Applicants respectfully traverse with respect to claim 27, as previously presented, in which the system requires an electrode adapted to be attached to a portion of the patient's body remote from the vagus nerve for indirect stimulation. The apparatus of Wernecke describes a bipolar stimulation electrode assembly coupled to a pulse generator, and which is adapted for direct attachment to the vagus nerve in the neck of the patient. There is no teaching of indirect stimulation of the vagus nerve.

Neither does *Wernecke* teach an apparatus comprising two separate electrodes adapted for administering bilateral stimulation to both the left and right branches of the vagus nerve at near-diaphragmatic locations, to treat a neuropsychiatric disorder. Claim 23 is currently amended

#### Response to Office Action dated June 7, 2006

to require that at least two electrodes are coupled to the pulse generator and are adapted for coupling, respectively, to the right and left branches of the vagus nerve in a near-diaphragmatic location for delivering a predetermined sequence of electrical pulses to ameliorate symptoms of the neuropsychiatric disorder. The claim amendments are supported in the specification at page 7, lines 1-4; page 7, line 20–page 8, line 1; and Figs. 1–4, for example. A pulse generator adapted (*e.g.*, programmed) for treating a neuropsychiatric disorder is different

Claim 25 is currently amended to require that the electrodes are adapted for attachment to the left and right branches of the vagus nerve, respectively, for <u>direct</u> stimulation.

Claim 27, as currently amended, requires at least two electrodes adapted to be attached remotely from the right and left branches of the vagus nerve for <u>indirect</u> stimulation.

Claims 30 and 34 are currently amended similarly to claim 23 and are likewise supported in the specification. Claim 34 is further amended to require that the at least two electrodes are coupled, respectively, to the right and left branches of the vagus nerve, as would be the case when the apparatus is used for the stated purpose of treating a neuropsychiatric disorder.

Applicants respectfully submit that claims 23–25 and 27–37, as currently amended, distinguish over *Wernecke*.

#### **Additional Amendments**

Claims 26 is canceled without prejudice to being reintroduced later in a continuing application.

Claim 28 is currently amended for consistency with amended claim 23, and is supported by the original claims as filed and as stated above with respect to claim 23.

Claim 32 is currently amended for consistency with amended claim 30

Claim 36 is currently amended to correct an inadvertent typographical or transcriptional error. The requirement that a "programming unit is external to the body of the patient and is wirelessly coupled to said at least one electrode" is supported in the original claim and in the specification at page 10, lines 4–6 and page 16, lines 12–15, for example.

# **Conclusion**

This Response to final Office Action is filed in conjunction with a Request for Continued Examination. Reconsideration of the application and withdrawal of the rejections are requested in light of the foregoing amendments and remarks. Applicants request allowance of all pending claims. This is believed to be a full and complete response to the Office Action dated June 7, 2006. If any issue in the Office Action has been overlooked or is deemed to be

**Application No.: 10/661,641** 

Response to Office Action dated June 7, 2006

incompletely addressed. Applicants respectfully request the opportunity to supplement this response. It is believed that no extensions of time or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event that any additional extension of time is necessary to allow consideration of this paper, such extension is hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required (including fees for net addition of claims) are hereby authorized to be charged to Deposit Account Number 503053 of Cyberonics, Inc., Houston, Texas.

Respectfully submitted.

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